# SOPP 8001.6: Procedures for Parallel Scientific Advice with European Medicines Agency (EMA)

Version #2

Effective Date: December, 1, 2013

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## I. Purpose

The purpose of this document is to describe the policies and procedures to be used by Center for Biologics Evaluation and Research (CBER) staff when considering and/or undertaking Parallel Scientific Advice (PSA) with the European Medicines Agency (EMA).

## II. Scope

The scope of this document is the formal program known as *PSA* in which a sponsor seeks parallel scientific advice from FDA and EMA on issues related to the development phase of a new product. The products eligible for this process specific to the EMA-CBER interactions are: cell therapies, gene therapies, tissue engineered products (Advanced Therapy Medicinal Products), vaccines, and plasma derivatives.

## III. Background

**A.** On September 17, 2004, the EMA and the FDA agreed to undertake a pilot program to provide parallel scientific advice (PSA). Since the initiation of the pilot program on January 1, 2005, PSA activities have significantly increased. This increase in PSA activities led to an indefinite extension of the PSA program on March 13, 2006.

**B.** For the FDA, the PSA aligns most closely to pre-IND or end of Phase II meetings, depending on the stage of product development. A sponsor submits questions to both agencies in order to receive scientific advice representing the outcome of joint scientific deliberations between the two agencies. The agencies confer prior to meeting with the sponsor. During the sponsor meeting each agency provides responses to the questions. Separate written responses are provided by each agency at the conclusion of the PSA.

**C.** The benefits of these interactions include:

**1.** an increased dialogue between the two agencies and sponsors at various points of the lifecycle of a new product,

**2.** a deeper understanding of the bases of scientific advice, and

**3.** an opportunity to optimize product development and avoid unnecessary replication of testing or unnecessary divergence in testing methodologies.

**D.** These meetings are conducted under the auspices of the confidentiality arrangement between the European Commission, the EMA, and FDA set forth in the FDA Staff Manual Guide *SMG 2830.3: Sharing Non-Public Information with Foreign Government Officials.*

## IV. Definitions

**A. Agencies' Liaisons -** refers to the FDA and EMA central points of contact to whom Sponsors submit requests for PSA. This definition wasn't added to the glossary

**B. Parallel Scientific Advice (PSA) -** refers to an exchange of views on scientific issues during the development phase of eligible human drugs and biologic products.

**C. Prescription Drug User Fee Act (PDUFA) -** A United States law enacted in 1992, which is periodically reviewed and revised, authorizing FDA to collect fees from companies that apply for approval and market certain human drug and biological products. The fees are used to hire review staff and for other related drug and biologic review purposes so that application review timeline goals can be met.

**D. Scientific Advice Working Party (SAWP) -** the standing working party to the Committee of Human Medicinal Products (CHMP) at the EMA that participates in the PSA. **Note:** The SAWP is comprised of experts from EU member states and meets once a month for 3-4 days. This definition wasn't added to the glossary

**E. Sponsor -** refers to (a) the "sponsor" of an Investigational New Drug Application (IND) in the US, (b) the "applicant" that submits a New Drug Application (NDA) or Biologics License Application (BLA) in the US, or (c) a potential marketing authorization applicant (MAA) under the marketing authorization process in the European Union. There are 2 definitions for sponsor in the glossary – this one and the one from the CFR regarding investigational products.

## V. Policy

**A.** The PSA process is voluntary and is usually initiated at the sponsor's request. A PSA may also be initiated by either the EMA or FDA in cooperation with the sponsor.

**B.** The PSA should focus primarily on specific questions or issues involving the development of an eligible product for which the sponsor desires to have further scientific input from both EMA and FDA.

**C.** A PSA is intended to address a single set of questions submitted by a sponsor, and should not be viewed as an ongoing series of consultations.

**D.** The PSA takes place under the provision of the confidentiality arrangement between the FDA and EMA and with the sponsor's authorization.

**E.** Each agency will provide, according to its usual procedures, independent advice to the sponsor on the questions posed during the PSA. Following joint discussion, the two

agencies' advice may differ. Sponsors should not necessarily expect to receive the same recommendations from both agencies regarding product development issues or marketing applications that have undergone PSA. It is anticipated that following a PSA, sponsors should have a clearer understanding of the agencies' respective requirements and perspectives with regard to the development program discussed, and, if divergent, the reasons for the divergence.

**F.** Both agencies remain committed to meeting domestic process and review goals and timeframes. As envisioned, the PSA procedures should not adversely affect either agency's ability to meet formal domestic performance expectations. Therefore, each agency shall be cognizant of the other's formal domestic performance expectations and be as flexible as possible in scheduling PSA meetings to fulfill those requirements.

**G.** The PSA Product Office Lead should assure that the sponsor identifies a single Point of Contact (POC) for the PSA.

**H.** The relevant CBER product office will have a "PSA Product Office Lead" who is responsible for coordinating the PSA per office procedure. An office may choose to have an established designated lead, or to identify a specific lead with each request.

**I.** If the CBER product office is contacted directly by the sponsor, the product office should notify the CBER Senior Advisor for International Affairs (SAIA), and the SAIA will undertake further appropriate communication.

**J.** A decision by the CBER product office on whether to initiate a PSA or not should be made within 14 days of CBER receipt of the PSA meeting request.

**K.** PSA meetings will generally occur via tele- or video-conference. On rare occasions, staff from one agency may travel to the other agency for such meetings. Such travel should be at the expense of the agency for which the traveler is employed. Typically, meetings to be scheduled for each PSA will include:

1. Internal meetings with FDA participants only.

2. One or more joint scientific meetings with the SAWP to discuss the questions submitted by the sponsor.

3. The concluding meeting between the SAWP, the FDA, and the sponsor after which the scientific advice is provided according to each agency's process timelines.

**L.** Meetings with the SAWP will need to be held on dates that conform to its schedule. The CBER Foreign Regulatory Communications Coordinator (FRCC) will provide the SAWP calendar to the product office PSA Lead to facilitate scheduling. In addition, due to time differences, meetings with the SAWP must start between 8:00 a.m. and 12:00 p.m. Eastern Time.

**M.** In certain circumstances, the SAWP or FDA may find it appropriate to NOT meet with the sponsor at the same time. In those cases, separate meetings with the company may be

held after internal consultation. If either the SAWP or FDA believes that a joint meeting should not be held with the sponsor, they will notify each other. In the case of the SAWP, they will notify FDA of this determination after their "Day 30" meeting.

**N.** CBER staff making reference in a review to any non-public information shared by foreign government officials under FDA's confidentiality commitments must provide appropriate reference information in the review such that future readers know the source of information is confidential. The source document or information itself should not be included in the review file, but rather a memorandum should be included which states the document or information was shared under FDA's confidentiality commitments. The memorandum should include the date the source document or information was shared and state that the document is archived in the CBER FRCC Confidential Foreign Communications Database.

## VI. Responsibilities

### A. Liaisons for FDA and EMA

**1.** Contacts the primary POC in CBER (SAIA, see below) for further management of each PSA request.

### B. CBER Immediate Office of the Director (IOD)

**1.** Senior Advisor for International Affairs (SAIA)

**a.** Oversees the PSA procedure within CBER. The SAIA is supported by the CBER Foreign Regulatory Communications Coordinator (FRCC).

**2.** Foreign Regulatory Communications Coordinator (FRCC)

**a.** In conjunction with the PSA lead in the relevant product office, the FRCC is responsible for executing the procedure.

**b.** Secures sponsor authorization to permit a comprehensive inter-agency exchange of all information relevant to the subject product, specifically including trade secret information (as defined by SMG 2830.3).

**c.** Ensures the authorization is reviewed for adequacy per established procedures governing confidentiality arrangements.

**d.** Coordinates with a designated PSA lead in the relevant product office (see below).

### C. CBER Offices

**1.** The relevant product office identifies a PSA Product Office Lead.

2. Ensures the office tracks the PSA using the appropriate CBER database. [PSA Product Office Lead]

## VII. Procedures

### A. Request for a Meeting

1. Forward any request that pertains to a CBER-regulated product to CBER's SAIA. **[Deputy Director, FDA Europe Office Liaison to EMA (DDEO)]**.

2. Confirm PSA requests were sent simultaneously to the designated Agencies' Liaisons. Any questions regarding a PSA meeting request submission should be referred to the Agencies' Liaisons [Listing in Appendix A]. **[CBER FRCC]**

### B. Assessing request for acceptance

1. Refer the meeting request for the PSA to the appropriate product office [either the established PSA Product Office Lead or the Office Director]. **[CBER FRCC]**

2. Assess the request within 14 days of CBER receipt to determine whether to undertake the PSA. **[Product Office]**

    **a.** Requests for a PSA can be denied based upon timing and/or workload constraints or appropriateness of the product for the PSA procedure. If a sponsor's request for parallel scientific advice is not granted, the Office Director or the PSA Product Office Lead should contact the sponsor with a copy to the CBER FRCC.

    **b.** If FDA decides to accept a PSA request, the process below is initiated.

3. Communicate the final decision to the sponsor and notify the CBER FRCC. **[Product Office]**

### C. The conduct of the PSA

1. Contact the product office PSA Lead **[CBER FRCC]**

    **a.** If a product office has a permanent designated lead for all PSAs, the FRCC will contact that individual.

    **b.** If a product office does not have a permanent designated lead, the FRCC will notify the Office Director of the request in order to identify a PSA Lead for the request under consideration.

2. Obtain sponsor authorization to undertake the PSA. **[CBER FRCC]**

3. Confer to outline the appropriate steps for managing the PSA once the request is accepted by the EMA and the FDA. **[Product Office PSA Lead and CBER FRCC]**

    **a.** These steps include determining responsibilities for scheduling meetings/teleconferences and information exchanges for the specific PSA.

    **b.** The PSA meeting integrates into the regular SAWP meeting/review process. It is intended that the FDA and SAWP will hold a scientific discussion of the PSA questions during the regular SAWP meeting that takes place at approximately "Day 30."

    **c.** The concluding meeting with the sponsor and the two Agencies will coincide with the SAWP meeting at approximately "Day 60" of its established process (see Reference 5 Pages 27-28).

4. Enter minutes for the internal and external meetings in the appropriate CBER regulatory database and import into CBER's Electronic Document Room (EDR). **[Product Office PSA Lead]**

5. CBER Review Memos: **[Product Office PSA Lead]**

    **a.** Confirm that CBER staff referencing any non-public information shared by foreign government officials under FDA's confidentiality commitments provide appropriate reference information in a review memo to ensure future readers know the source of information is confidential.

    **b.** The source document or information itself should not be included in the review file, but rather a memorandum should be included which states the document or information was shared under FDA's confidentiality commitments.

    **c.** The memorandum should include the date the source document or information was shared and state that the document is archived in the CBER FRCC Confidential Foreign Communications Database.

## VIII. Appendix

**A.** Appendix 1: Point of Contacts for FDA/EMA/PSA meetings

## IX. References

**A. Web links to the references below can be found in the list following the History Table**

1. Prescription Drug User Fee Act (PDUFA): http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm

2. General Principles EMA-FDA Parallel Scientific Advice Meetings Pilot Program: http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/EuropeanUnion/EuropeanUnion/EuropeanCommission/ucm114345.htm

3. SOPP 8101.1 Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm

4. Staff Manual Guide (SMG) 2830.3 Sharing of Non-Public Information with Government Officials http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm188284.htm

5. European Medicines Agency Guidance for Companies requesting Scientific Advice and Protocol Assistance http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004089.pdf

## X. History

| Written/ Revised | Approved By | Approval Date | Version Number | Comment |
|---|---|---|---|---|
| Judith Arcidiacono, M.S.<br>Judith Badoo, M.S.<br>Joan Wilmarth Blair, M.A. | Robert A. Yetter, PhD. | Nov 15, 2013 | 2 | Revision to incorporate new procedures |
| Joan Wilmarth Blair, M.A. | Robert A. Yetter, PhD. | November 13, 2006 | 1 | First issuance of this SOPP |